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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,975

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Anthony John Clark

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MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

SINGH, ANOOP KUMAR

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

12/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,975	Applicant(s) CLARK ET AL.	
	Examiner ANOOP SINGH	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 31-42 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10, 16-18 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-8, 11-15, 19-27, 31-39, 41 and 42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response and amendments to the claims filed September 10, 2009, have been received and entered. Applicants have amended claims 1-3, 5, 31-33, while claims 28-30 have been canceled. Applicants have newly added claims 41-42, which are generally directed to elected invention.

Applicants' election of with traverse, of claims 1-8, 11-15, 19-20, 26-27, 31-39(Group II), drawn to a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a reporter protein that is secreted is a human beta choriogonadotrophin (hCG), a host cell comprising the nucleic acid of the invention and method of using cell for *in vitro* screening was acknowledged. Upon further consideration, claims 21-25 (group VI) directed to transgenic mouse comprising a nucleic acid sequence encoding a reporter protein that is secreted is a modified human beta choriogonadotrophin (hCG) were rejoined with the elected invention of claims 1-8, 11-15, 19-20, 26-27, 31-39 (group II). The requirement for restriction was deemed proper, maintained and hereby made FINAL.

Claim 9-10, 16-18, 40 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/23/2009.

It is noted that, in response to office action dated June 10, 2009, applicants have amended independent claims 1 and 41 to include a construct comprising a nucleic acid encoding a secretable reporter protein and an inducible promoter that drives the production or expression of said reporter protein, while claim 41 requires producing reporter protein as a result of one or more of the following: (i) disturbances in the homeostatic state of DNA; (ii) oxidative stress or hypoxia; (iii) hepatotoxic stress; (iv) presence of a pro-apoptotic stimulus; (v) administration of chemical, drugs, or other xenobiotic agents; (vi) disease onset, either natural, modeled or induced, that was not previously presented. Accordingly, a new election of species is required in view of amendments to the claims 1 and 41 that are generic to the type of inducible promoter. .

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It is noted that 37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied. *Ex parte Benke*, 1904C.D. 63, 108 O.G. 1588 (Comm'r Pat. 1904).

Claims 1-8, 11-15, 19-27, 31-39, 41 and 42 are subject to further restriction in view of Applicants' amendment to the claims.

Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: inducible promoter that may be selected from following inducible genes: whose expression is modified in response to (i) disturbances in the homeostatic state of DNA, ii) oxidative stress or hypoxia; (iii) hepatotoxic stress; (iv) presence of a pro-apoptotic stimulus; (v) administration of chemical, drugs, or other xenobiotic agents; (vi) disease onset, either natural, modeled or induced.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claims 1 and 41, and claims dependent therefrom correspond to all the species listed above.

The following claims are generic: 1 and 41.

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: since each of these inducible promoter type do not share a common structure feature in common with respect to their action and therefore would not be co-extensive in patent and non patent literature. Thus, requirement of unity of invention is not fulfilled.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANOOP SINGH whose telephone number is (571)272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anoop Singh/
Examiner, Art Unit 1632